



Dkt. #627-B-US *IFW*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Vladimir BAKHUTASHVILI
U.S. Serial No.: 10/795,819 Examiner: Ruth A. Davis
Filed : March 8, 2004 Art Unit: 1651
For : AMNIOTIC APOPTOSIS MODULATING SUBSTANCES

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Whitestone, New York 11357

October 7, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-145

Sir/Madam:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with his duty of disclosure under 37 C.F.R. §1.56, Applicant would like to direct the Examiner's attention to the following references which are listed below and on Form PTO/SB/08B (**Exhibit A**, 3 pages), with the individual references further attached as **Exhibits 1-21**.

1. Nahar, et al., "Infliximab Treatment of Rheumatoid Arthritis and Crohn's Disease", *The Annals of Pharmacotherapy*, Vol. 37, pgs 1256-1265 (2003) [**Exhibit 1**]
2. Watanabe, et al., "Concanavalin A Induces Perforin-Mediated But Not Fas-Mediated Hepatic Injury", *Hepatology*, Vol. 24, No. 3, pgs 702-710 (1996) [**Exhibit 2**]
3. Xiang, et al., "Prevention by rolipram of concanavalin A-induced T-cell-dependent hepatitis in mice", *European Journal of Pharmacology*, Vol. 367, pgs 399-404 (1999) [**Exhibit 3**]

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4. Dzotsenidze, et al., "The Antitoxic Effect of Plaferon LB on Pesticides in Tissue Culture Model", Annals of Biomedical Research and Education, Vol. 3, pgs 180-182 (2003) **[Exhibit 4]**
5. Maisuradze, et al., "Some Aspects of Protective Effect of Plaferon LB During Bronchial Asthma", Annals of Biomedical Research and Education, Vol. 3, pgs 189-191 (2003) **[Exhibit 5]**
6. Kvezereli, et al., "Effects of Plaferon LB (PLB) on concanavalian A- induced hepatitis in mice", Annals of Biomedical Research and Education, Vol. 2, pgs 133-138 (2002) **[Exhibit 6]**
7. Bakradze, et al., "The Perioperative Immunocorrection by Plaferon for Colorectal Cancer Patients", Annals of Biomedical Research and Education, Vol. 2, pgs 38-41 (2002) **[Exhibit 7]**
8. Chichua, et al., "Biochemical Changes in Retinal Tissue During Vitreoretinal Pathology", Annals of Biomedical Research and Education, Vol. 2, pgs 189-195 (2002) **[Exhibit 8]**
9. Bach, Jean-Francois, "Immunotherapy of type 1 diabetes: lessons for other autoimmune diseases", Arthritis Res, Vol. 4, pgs S3-S15 (2002) **[Exhibit 9]**
10. Nicoletti, et al., "The Effects of a Nonimmunogenic Form of Murine Soluble Interferon-gamma Receptor on the Development of Autoimmune Diabetes in the NOD Mouse", Endocrinology, Vol. 137, No. 12, pgs 5567-5575 (2005) **[Exhibit 10]**

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11. Nicoletti, et al., "Early Prophylaxis with Recombinant Human Interleukin-11 Prevents Spontaneous Diabetes in NOD Mice", *Diabetes*, Vol. 48, pgs 2333-2339 (1999) **[Exhibit 11]**
12. Lobzhanidze, et al., "Positive Effect of Plaferon-LB on Treatment of Hodgkin's Disease-Result of Immunocorrection or Apoptosis", *Annals of Biomedical Research and Education*, Vol. 1, pgs 170-173 (2001) **[Exhibit 12]**
13. Sharma, et al., "Usefulness of Gamma Intracoronary Radiation for Totally Occluded In-Stent Restenotic Coronary Narrowing", *The American Journal of Cardiology*, Vol. 91, pgs 595-597 (2003) **[Exhibit 13]**
14. Jessup, et al., "Heart Failure", *The New England Journal of Medicine*, Vol. 348, pgs 2007-2018 (2003) **[Exhibit 14]**
15. Nicoletti, et al., "Prevention and Treatment of Lethal Murine Endotoxemia by the Novel Immunomodulatory Agent MFP-14", *Antimicrobial Agents and Chemotherapy*, Vol. 45, No. 5, pgs 1591-1594 (2001) **[Exhibit 15]**
16. Genovese, et al., "Improved Survival and Antagonistic Effect of Sodium Fusidate on Tumor Necrosis Factor Alpha in a Neonatal Mouse Model of Endotoxin Shock", *Antimicrobial Agents and Chemotherapy*, Vol. 40, No. 7, pgs 1733-1735 (1996) **[Exhibit 16]**
17. Nicoletti, et al., "Endotoxin-Induced Lethality in Neonatal Mice is Counteracted by Interleukin-10 (IL-10) and Exacerbated by Anti-IL-10", *Clinical and Diagnostic Laboratory Immunology*, Vol. 4, No. 5, pgs 607-610 (1997) **[Exhibit 17]**

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18. Nicoletti, et al., "Protection from concanavalin A (Con A)-induced T cell dependent hepatic lesions and modulation of cytokine release in mice by sodium fusidate", Clin Exp Immunol, Vol. 110, pgs 479-484 (1997) **[Exhibit 18]**
19. Mizuhara, et al., "T Cell Activation-associated Hepatic Injury: Mediation by Tumor Necrosis Factors and Protection by Interleukin 6", J. Exp. Med, Vol. 179, pgs 1529-1537 (1994) **[Exhibit 19]**
20. Tiegs, et al., "A T Cell-dependent Experimental Liver Injury in Mice Inducible by Concanavalin A", J. Clin. Invest., Vol. 90, pgs 196-203 (1992) **[Exhibit 20]**
21. Nicoletti, et al., "Murine Concanavalin A-Induced Hepatitis is Prevented by Interleukin 12 (IL-12) Antibody and Exacerbated by Exogenous IL-12 Through an Interferon-gamma-Dependent Mechanism", Hepatology, Vol. 32, No. 4, pgs 728-733 (2000) **[Exhibit 21]**

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If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

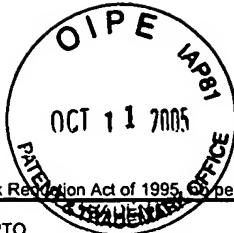
Respectfully submitted,

Albert Wai-Kit Chan

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| | | | | Filing Date | March 8, 2004 |
| | | | | First Named Inventor | BAKHUTASHVILI, Vladimir |
| | | | | Art Unit | 1651 |
| | | | | Examiner Name | Ruth A. Davis |
| Sheet | 1 | of | 3 | Attorney Docket Number | |
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| | 1 | Nahar, et al., "Infliximab Treatment of Rheumatoid Arthritis and Crohn's Disease", <i>The Annals of Pharmacotherapy</i> , Vol. 37, pgs 1256-1265 (2003) | |
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| | | | | Art Unit | 1651 |
| | | | | Examiner Name | Ruth A. Davis |
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| | 11 | Nicoletti, et al., "Early Prophylaxis with Recombinant Human Interleukin-11 Prevents Spontaneous Diabetes in NOD Mice", Diabetes, Vol. 48, pgs 2333-2339 (1999) | | | |
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